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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61J 1/00, A61M 5/31 — A1

(11) International Publication Number: **WO 99/22691**

(43) International Publication Date: 14 May 1999 (14.05.99)

(21) International Application Number: PCT/US98/22464

(22) International Filing Date: 22 October 1998 (22.10.98)

(30) Priority Data:
08/962,000 31 October 1997 (31.10.97) US

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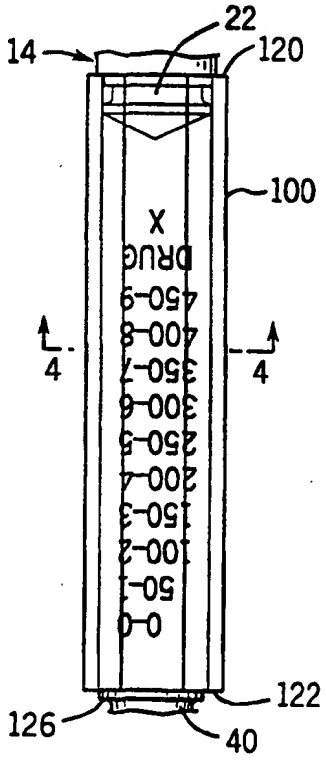
(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: SYSTEM FOR STORING OXYGEN SENSITIVE COMPOSITIONS

(57) Abstract

A system is provided for storing a composition, and the system includes structure for preventing gas migration into or out of the system. The system includes a container adapted for containing the composition. The container has an exterior which includes a sidewall structure through which gas can migrate. The sidewall structure has an outer surface. In a preferred embodiment, the structure includes a laminate of multiple layers of materials which provides an oxygen barrier and is mounted to at least a portion of the outer surface of the container for preventing substantial oxygen migration through a major portion of the container exterior by exhibiting a relatively low oxygen permeability compared to the sidewall structure of the container.



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SYSTEM FOR STORING OXYGEN SENSITIVE COMPOSITIONS

CROSS REFERENCE TO RELATED APPLICATION(S)

Not applicable.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not applicable.

REFERENCE TO A MICROFICHE APPENDIX

Not applicable.

TECHNICAL FIELD

The present invention relates to a system for storing compositions. The present invention is especially suitable for syringes and containers, including vials, ampules, and the like, containing solid or liquid pharmaceutical drugs, medicaments, or other products.

BACKGROUND OF THE INVENTION AND TECHNICAL PROBLEMS POSED BY THE PRIOR ART

Many products, especially medical or pharmaceutical compositions, are delivered to pharmacies in sealed containers such as plastic vials, plastic bottles, plastic ampules, and plastic syringes. Such containers can contain a liquid drug, a powdered or lyophilized formulation of a pharmaceutical product that may be administered directly or may be reconstituted prior to administration to a patient, or other medicament or composition that is intended to be administered to a patient, either internally or externally.

Some compositions are characterized as being oxygen-sensitive. Such compositions are deleteriously affected when subjected to oxygen over a period of time, including oxygen in the normal concentration in ambient air. For example, over a period of time, oxygen may affect the

potency or efficacy of a drug. Thus, if an oxygen-sensitive drug or other composition is manufactured and stored in a container for a period of time, the container should include provisions to minimize the ingress of oxygen.

Some containers, such as glass containers, may provide a sufficient oxygen barrier for many oxygen-sensitive compositions over the intended or normal shelf lives of such compositions. However, glass containers and containers made from other materials providing an oxygen barrier may not be desirable in some applications. For example, glass or other materials that provide a good oxygen barrier may be relatively costly to use in the manufacture of certain, specialized containers, including disposable containers for pharmaceutical products. Some materials, glass, for example, may be more susceptible to breakage compared to other materials that lack good oxygen barrier properties.

Some thermoplastic materials, such as polyester, are relatively inexpensive and easy to mold into containers. However, polyester cannot withstand steam sterilization to which containers of pharmaceutical compositions are typically subjected. Further, many materials, such as polyester, are not sufficiently inert with respect to pharmaceutical drugs or other compositions. If the container material is not sufficiently non-reactive or inert, some chemical components of the material may react with, or migrate into, the drug or other composition. Such container materials are characterized as having an unacceptable high level of extractables that prevent the use of such materials as containers for long-term storage of certain products, such as some drugs or other compositions.

Polypropylene is a thermoplastic material which is suitable for use as a syringe or a container for many types of drugs because it is relatively inexpensive, because it can withstand steam sterilization, and because it does not have significant extractables which react with, or migrate into, many compositions, such as many pharmaceutical drugs. However, polypropylene is relatively permeable to oxygen at atmospheric pressure and therefore does not provide a very good barrier to oxygen migration. Thus, when a polypropylene container is stored, a significant

amount of oxygen can migrate over time through the container and into the composition contained within the container. An oxygen-sensitive composition could be deleteriously affected.

A variety of overwraps or other secondary package materials have been provided to reduce the oxygen migration into a composition contained within a polypropylene container or container of other material which does not provide an inherently high barrier to oxygen migration. For example, pouches or bags made from aluminum foil laminates or metalized films have been used, or proposed for use, in packaging primary containers of oxygen-sensitive drugs, such as polypropylene syringes. While such pouches or bags may provide a sufficient oxygen barrier, the use of such pouches or bags is not without disadvantages. For example, a metal foil laminate or metalized film is typically opaque. Thus, the user cannot see through the pouch or bag to determine the condition of the primary storage container and to read the label on the primary storage container.

Also, the pouch or bag must be separately opened to provide access to the primary container. Further, the opened pouch or bag must then be discarded. Typically, the primary container, such as an ampule or syringe, is discarded after use in a special bio-hazard waste receptacle. However, a secondary overwrap pouch or bag must be discarded in a separate waste receptacle.

While a polypropylene ampule or syringe may be incinerated, an aluminum foil laminate pouch or bag is not typically incinerated. Thus, the pouch or bag ultimately contributes to landfill waste (i.e., "solid waste").

In view of the disadvantages of separate, secondary pouch or bag oxygen barriers, including those disadvantages discussed above, it would be desirable to provide an improved system for storing oxygen-sensitive compositions. Such an improved system should preferably eliminate or minimize the creation of additional waste material that must be disposed of separately from a primary container. Additionally, such an improved system should beneficially permit the overall size of the package to be as small as possible so as to minimize the cost as well as the amount of waste to be disposed of after use.

Further, such an improved system should advantageously provide an oxygen barrier before, during and after use of the primary container. If the contents of the primary container are not completely used, and if the partially empty container is stored for subsequent re-use, the improved system should preferably still provide a barrier to oxygen migration through the container.

Also, such an improved system should permit the visual inspection or observation of the container contents before use and during use so as to enable the user to determine the amount of the composition still remaining in the container at any point in time.

An improved system for storing oxygen-sensitive compounds should also accommodate steam sterilization, or other sterilization techniques, after the composition, such as a drug, has been sealed within the system.

Additionally, it would be desirable if such an improved system would provide sufficient strength, impact resistance, and structural integrity to withstand various conventional or special manufacturing, storage, and handling activities.

Finally, it would be desirable if such an improved system could accommodate the application or use of a label within the system in a way that would permit visual observation of the label during use and also during storage.

The present invention provides an improved system for storing oxygen-sensitive compositions, and the improved system can accommodate designs having the above-discussed benefits and features.

SUMMARY OF THE INVENTION

According to the present invention, a system is provided for storing a composition which can be deleteriously affected by oxygen. According to one aspect of the invention, the system includes a container which is adapted for containing a quantity of the composition. The container has an exterior which is defined at least in part by a sidewall structure through which the oxygen can migrate. The sidewall structure

has an outer surface defining part of the container exterior. The system includes means for providing a barrier mounted to at least a portion of the outer surface for preventing substantial oxygen migration through a major portion of the container exterior by exhibiting a relatively low oxygen permeability compared to the underlying sidewall structure.

According to yet another aspect of the invention, the system includes a container which is adapted for containing a quantity of a composition and which has an exterior. The container has a sidewall structure through which oxygen can migrate. The sidewall structure defines an outer surface having at least a first predetermined area which is a major portion of the container exterior. A film is secured in face-to-face contact with the outer surface over the first predetermined area. The film has a relatively low oxygen permeability so as to provide a barrier to substantial oxygen migration.

In a preferred form of the invention, the system includes a film formed as a laminate of multiple layers of materials. The laminate is secured with adhesive to the container.

The system is especially suitable for use with a polypropylene syringe wherein the syringe constitutes the container. A transparent laminate of multiple layers of materials is formed and printed with label information. The printed laminate is then applied around the body of the syringe and secured thereto with adhesive.

The syringe plunger grommet, typically manufactured from a thermoplastic elastomer or rubber, provides a suitable oxygen barrier at the upper end of the syringe. At the bottom end of the syringe, the outlet connection structure defines only a very small area through which oxygen could migrate. This area is so small, compared to the body of the syringe which is covered with the oxygen barrier laminate, that the amount of oxygen that can migrate into the composition contained within the syringe during the storage shelf life of the syringe is not great enough to deleteriously affect the composition.

The syringe with the adhered laminate provides a unitary storage system incorporating an oxygen barrier. No secondary oxygen barrier pouch or bag is required.

After use, the unitary system may be discarded in a bio-hazard waste receptacle and ultimately incinerated.

The system provides a self-contained, structurally rigid package which accommodates ease of storage and handling.

The contents of the syringe can be readily observed through the transparent laminate oxygen barrier both during storage and during use.

The laminate can be applied to the syringe with conventional label-applying apparatus and techniques. The system is significantly less costly than packages which employ a secondary pouch or bag for an oxygen barrier. The system creates less waste material than such bag or pouch packages.

Numerous other advantages and features of the present invention will become readily apparent from the following detailed description of the invention, from the claims, and from the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings that form part of the specification, and in which like numerals are employed to designate like parts throughout the same,

FIG. 1 is a perspective view of one type of a conventional plastic syringe which could be filled with an oxygen-sensitive composition;

FIG. 2 is a fragmentary, perspective view of an oxygen barrier laminate being applied to the body of the syringe;

FIG. 3 is a fragmentary, side elevational view of the final configuration of the laminate on the syringe after the laminate has been properly applied and secured to the syringe body;

FIG. 4 is a greatly enlarged, cross-sectional view taken generally along the plane 4-4 in FIG. 3; and

FIG. 5 is a very greatly enlarged, fragmentary, cross-sectional view taken generally along the plane 5-5 in FIG. 2 to illustrate the oxygen barrier laminate together with a release liner, and the thicknesses of some of the layers of the laminate relative to the thicknesses of other layers of the laminate are somewhat enlarged out of scale for ease of illustration.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

While this invention is susceptible of embodiment in many different forms, this specification and the accompanying drawings disclose only some specific forms as examples of the invention. The invention is not intended to be limited to the embodiments so described, however. The scope of the invention is pointed out in the appended claims.

For ease of description, a preferred embodiment of the system of this invention is described in one usual operating position, and terms such as upper, lower, horizontal, etc., are used with reference to this position. It will be understood, however, that the system of this invention may be manufactured, stored, transported, used, and sold in an orientation other than the position described.

FIG. 1 illustrates one type of a conventional, disposable, plastic syringe 12. A hollow needle (not illustrated) may be attached to the syringe 12 when the user desires to dispense a fluid, such as a liquid drug, medicament, or other composition from the syringe 12. Such a composition may be initially supplied in the syringe to a hospital or medical professional. Note that the syringe 12 can also be directly attached to a fluid administration set.

The syringe 12 includes a barrel or body 14 with a finger-engageable member 16 at one end thereof. The syringe 12 also includes a plunger 18 which has an elongate shank 20 disposed for reciprocating movement in the syringe barrel 14. A plunger head, piston, or grommet 22 is threadably attached, or otherwise suitably secured, to the distal end of the plunger shank 20. The plunger or grommet 22 is formed of rubber or the like and is of such diameter as to frictionally engage the interior of a

bore defined in the syringe barrel 14. The proximal end of the plunger shank 18 terminates in a thumb rest 24.

Both the syringe barrel 14 and the plunger 18 are typically molded from a suitable thermoplastic material, such as polypropylene, which is generally transparent or translucent. However, the piston or grommet 22 is typically molded from an opaque rubber material or suitable synthetic, elastomeric polymer.

The distal end of the syringe barrel 14 defines the dispensing end 28. The conventional syringe barrel 14 illustrated in FIG. 1 has a dispensing end 28 which includes a conventional luer-lock type of fluid transfer connector designed in accordance with the International Standard ISO 594-2 (First Edition, 1991 05-01, Reference No. ISO 594-2: 1991(E)) as published by the International Organization for Standardization, Case postale 56, CH-1211 Genèva 20, Switzerland, and illustrated in Figure 1 of that standard. That standard, including Figure 1 thereof, is incorporated herein by reference thereto. That standard sets forth the design criteria for a male 6% (Luer) conical lock fitting with a permanently connected internally threaded collar, and such a structure defines the dispensing end 28 of the syringe as shown in FIG. 1 herein.

In particular, a male nozzle 30 projects outwardly from the distal end of the syringe barrel 14. The nozzle 30 defines an internal bore 32 which establishes communication between the exterior of the syringe barrel 14 and the interior of the syringe barrel.

The nozzle 30 has an exterior, frustoconical surface 34 which may be characterized as defining a 6% conical taper on the diameter. That is, there is a 0.060 inch/inch taper on the diameter. This can be calculated by measuring the exterior diameter at a first location along the length of the nozzle 30 and by measuring a second exterior diameter at a second location along the length of the nozzle 30. The difference between the two diameters is divided by the distance between the locations of the two diameters, and the dividend is multiplied by 100 to yield the percent conical taper.

The nozzle 30 is surrounded with an annular collar 38 which has a generally cylindrical, exterior surface 40 and which has a double-start, right-hand, internal thread 42. The collar 38 is shorter than the nozzle 30. That is, the distal end of the nozzle 30 extends outwardly beyond the distal end of the collar 38.

The double-start, internal thread 42 has a steeply pitched, spiral configuration and is adapted to threadably engage the four corners of a square flange provided on a hub (not illustrated) of a hypodermic needle. The needle hub is typically molded from thermoplastic material, and the hub defines a female recess having a 6% Luer conical taper for matingly engaging the syringe nozzle 30 in a sealing relationship.

Typically, however, the syringe 12 is initially provided to the user without the needle attached. The dispensing end of the syringe 12 may instead be initially occluded and sealed with a suitable cap 50. The capped syringe 12 may be provided to the user prefilled with a sterile medicament or other composition. After the cap 50 is removed from the dispensing end of the syringe 12, a needle can be installed on the syringe 12 to permit the prefilled medicament to be dispensed, or the syringe 12 may be directly attached to a fluid administration set.

The cap 50 may be advantageously employed to maintain a sterile, sealed condition of the syringe nozzle 30 and of the thread space defined within the outer collar 38. A preferred embodiment of the cap 50 is molded as unitary structure from a resilient or pliant material. One presently preferred material is a butyl rubber, such as the Ashland brand rubber, grade No. 5212, manufactured in the United States of America by Abbott Laboratories, Inc., 268 East Fourth Street, Ashland, Ohio 44805, U.S.A. Such a material has been found to withstand steam sterilization processes and exhibits long term stability with typical syringe barrel materials, such as polypropylene. The rubber material also is stable when in contact with a variety of common medicaments or other fluids that are typically packaged in prefilled syringes.

When the syringe body 14 is made from polypropylene or other material which is significantly permeable to oxygen, a composition

stored within the syringe body 14 for a period of time will be subjected to oxygen migrating through the wall of the body 14. If the composition stored within the syringe body 14 is sensitive to oxygen, the composition can be deleteriously affected or degraded over time. The present invention includes means for providing a barrier to gas migration (ingress or egress) and especially for providing a barrier to gases such as oxygen or carbon dioxide. In the preferred embodiment of the invention, multiple layers of materials in the form of a laminate 100 are applied to, and adhered to, the syringe barrel 14.

FIG. 2 diagrammatically illustrates, in a simplified manner, a process by which a laminate 100 can be wrapped around the exterior surface of the syringe barrel or body 14. Preferably, the laminate 100 is wrapped completely around the circumference of the barrel or body 14 with a slight overlap (e.g., 0.5 inch), as indicated by the bracketed region 110 in FIG. 4.

The laminate 100 may be characterized as a sheet, web, or film which prevents substantial oxygen migration through the major portion of the container exterior by exhibiting a relatively low oxygen permeability compared to the sidewall structure of the syringe barrel or body 14.

It will be appreciated that the laminate 100 has a proximal, lateral edge 120 (FIG. 3) which is located adjacent the piston or grommet 22. The laminate 100 need not extend further beyond the grommet 22 because the grommet material (e.g., rubber or synthetic, elastomeric polymer) is typically substantially impermeable to oxygen and prevents significant ingress of oxygen--at least over the design shelf life period of a typical oxygen-sensitive drug or other composition.

The laminate 100 has a lateral edge 122 at the distal end of the syringe barrel or body 14. Preferably, the lateral edge 122 is located at, or very close to, the end of the barrel or body 14 from which the collar 38 projects. It will be appreciated that the barrel or body 14 defines a distally facing, annular surface 126 (FIGS. 1 and 3) which is not covered by the laminate 100. Also, there may be a small, annular portion of the surface 40

of the collar 38 which is not covered by the cap 50 or the laminate 100. The rubber or elastomeric polymer material of the cap 50 provides a substantial barrier to oxygen ingress over that portion of the syringe dispensing end 28 which is sealingly covered by the cap 50. The small, annular portion of the collar surface 40 which is not covered by the cap 50 and the small, annular shoulder 126 at the end of the syringe barrel or body 14 which is not covered by either the laminate 100 or the cap 50 together constitute a very small, external portion of the syringe through which oxygen can migrate. The amount of oxygen that can migrate through these small portions of the syringe over a typical design storage shelf life is so small that there is no significant deleterious effect on, or degradation of, the composition contained within the syringe.

However, if desired, even these small, exposed, external portions of the syringe distal end could be covered with a tight-fitting overcap (not illustrated) which could cover both the overcap and a small, annular portion at the end of the cylindrical surface of the syringe barrel or body 14. In one contemplated design, such an overcap could be made from a relatively thin, elastic rubber or elastomeric polymer having sufficient oxygen barrier properties. The overcap could be readily rolled down and off of the syringe at the time of use. Alternatively, an annular portion of a laminate material, with sufficient oxygen barrier properties, may be disposed on the exposed annular shoulder 126 of the syringe 12.

It will be appreciated that if such an overcap is not used, or if such an overcap is used but later removed, the laminate 100 nevertheless covers a major portion of the container exterior. More particularly, in the preferred embodiment illustrated, the cylindrical sidewall structure of the syringe barrel or body 14 may be characterized as having at least a first predetermined area which is a major portion of the container exterior, and the laminate may be characterized as being secured in face-to-face contact with the outer surface of the sidewall structure of the syringe body 14 over the first predetermined area.

A presently contemplated preferred form of the means for providing an oxygen barrier on the syringe barrel is illustrated in cross

section in FIG. 5. In the preferred embodiment, the means may be regarded as a composite film or laminate of layers of thinner films and other materials. The laminate 100 is typically relatively thin and may be generally characterized as a "film" notwithstanding the fact that preferably it comprises a plurality of thinner layers or films.

The laminate 100 includes a first layer 201, a second layer 202, a third layer 203, a fourth layer 204, a fifth layer 205, and a sixth layer 206. Typically, a release liner 207 is also provided on the bottom adjacent the sixth layer 206, and the release liner 207 is subsequently removed when the laminate 100 is applied to the syringe 12 or other container.

The first layer 201 is preferably an oriented polyester having a thickness A of 0.00048 inch. The first layer 201 preferably provides a surface for printing (e.g., receiving ink) for label information. The first layer 201 also protects the underlying layers.

Preferably, the exposed surface of the first layer 201 is corona-discharge treated to distress the surface (as schematically illustrated by reference number 210 in FIG. 5). Corona-discharge treatment is a well-known, conventional means for altering the surface of film, primarily by oxidation, to change surface polarity, and consequently the surface energy, in order to allow inks or adhesives or other materials to better wet the surface of the film. FIG. 5 illustrates ink 212 forming part of label information on the structure.

The second layer 202 is preferably a solvent-based adhesive for joining the first layer 201 and third layer 203. FIG. 5 shows the adhesive having a thickness B. It will be appreciated, however, that the adhesive may be conventionally applied with a roller to the film layer 201 so that the thickness B is almost negligible, perhaps only one tenth of the thickness of the first layer 201. One example of a suitable adhesive that may be employed is the adhesive sold under the Trademark ADCOTE-575 by Morton International, Inc., Adhesives and Chemical Specialties Division, 100 N. Riverside Plaza, IL. 60606-1292 U.S.A. The adhesive includes a polyester component of a two component laminating adhesive used in

conjunction with an isocyanate terminated co-reactant. The adhesive conforms to the U.S.A. Food and Drug Administration regulation 21 C.F.R. §175.105.

The third layer 203 preferably provides a substantial portion of the oxygen barrier properties of the laminate 100. The layer 203 is preferably an oriented polyester film which is coated with silicon oxide. The silicon oxide coating may be deposited by either evaporation or gas plasma deposition in a typical thickness range from between about 100 to about 2000 angstroms. The overall thickness C of the third layer 203, including the silicon oxide coating, is preferably about 0.00055 inch. Such a coated film may be a conventional film of the type sold under the designation Clear Foil Grade F by Rollprint Packaging Products, Inc. 320 Stewart Avenue, Addison, Illinois 60101-3375 U.S.A. Another silicon oxide-coated film that may be used is the film sold under the designation Ceramis by Lawson Mardon Packaging Co., 6850 Midland Industrial Drive, Shelbyville, Kentucky 40065 U.S.A. Other grades of the Clear Foil film may be employed, depending upon the application.

The fourth layer 204 is a solvent based adhesive for joining the third layer 203 to the fifth layer 205. The fourth layer 204 may have a thickness D and composition which are the same as the thickness B and composition, respectively, of the adhesive employed in the second layer 202.

The fifth layer 205 is preferably a transparent, biaxially-oriented polypropylene having a thickness E which is preferably about 0.002 inch. The fifth layer 205 functions to support the sixth layer 206. To this end, the lower surface of the fifth layer 205 is coated with a pressure-sensitive adhesive defining the sixth layer 206. The layer 206 has a thickness F which may be preferably substantially the same thickness as the thicknesses D and B of the second layer adhesive 202 and fourth layer adhesive 204, respectively. Preferably, the polypropylene fifth layer 205 and the pressure-sensitive adhesive sixth layer 206 are provided as part of a conventional label structure. The label structure also includes the release liner layer 207 which is preferably a polyester film that has a thickness G which may be about 0.0015 inch.

The layers 205, 206, and 207 may be characterized as a base label structure which is commercially available under the specification number 74326, with a pressure-sensitive adhesive (layer 206) designated E898, from Avery Dennison, Fasson Films Division, 250 Chester Street, Painsville, Ohio 44077 U.S.A. The base label structure pressure-sensitive adhesive (layer 206) is a permanent emulsion acrylic adhesive featuring initial high tack, high ultimate bond strength, and excellent mandrel hold on small-diameter containers, such as syringes and vials. The adhesive is crystal clear and remains clear throughout autoclave processing. It permits short-term repositioning on most substrates and forms an ultimate permanent bond.

The layers 201, 202, 203, and 204 can be readily assembled and formed into a first portion of the laminate 100 by one manufacturer. The laminated layers 201-204 can then be laminated to the laminate layers 205, 206, and 207 provided as a base label structure by a conventional label manufacturer. The methods for producing the film layers and laminate form no part of the present invention.

The completed laminate 100 would typically be provided in the form of a roll on a spool for use by the manufacturer of the syringe and/or drug. If desired, label information could also be printed on the surface 210 of the laminate 100. Conventional printing techniques may be employed, and these techniques form no part of the present invention.

A barrier label laminate of the above-identified layers 201-206 (but not the release layer 207) passes less than 0.01 cubic centimeters of oxygen per 100 square inches of material per day at 72°F. and 0% relative humidity. The laminate of layers 201-206 passes less than 0.02 grams of water per 100 square inches of material per day at 100°F. and 100% relative humidity.

In another contemplated embodiment of the laminate 100, the layers 201-205 may be initially formed as a first laminate portion wherein the layer 205 is either a 0.0005 inch thick polyester film layer or a 0.001 inch thick polyester film layer. The first laminate portion is then provided to a label manufacturer for applying the pressure-sensitive

adhesive layer 206 and a 0.0015 inch thick polyester release liner layer 207.

The completed laminate 100 can be converted into a printed label at a typical label conversion facility. The laminate 100 is provided to the conversion facility in a specific width that is necessary to provide the desired number of label impressions across the width of the roll. The roll of the laminate 100 is loaded onto a conventional combination printing and die-cut press (not illustrated). The roll of laminate is unwound and passed over a series of rollers to control tension. The laminate passes under a print roller that contains the necessary print copy, and the impression of the print copy is made on the exposed surface of the layer 201 of the moving laminate. The laminate material can move through additional print stations overlaying different color copy, if necessary, on top of previously applied print. The thickness of the print copy is considered negligible and does not contribute to the barrier properties of the printed laminate.

The printed laminate continues through the printing and die-cutting press where it is guided by tension rollers and directional control rollers to a die-cut section. A rotary die is used to cut the required individual label shape in proper registration with the print copy on the laminate. The die cuts through the laminate layers 201-206, but not through the release liner layer 207. The waste material forming the perimeter of the die cut label is typically peeled off, wound, and discarded. The printed and die-cut laminate on the uncut web of release liner layer 207 then continues through a final slitting station, if required, where the release liner web is cut and re-wound into single label-width rolls of finished laminate labels. The details of the method and apparatus for converting the laminate 100 to a roll of printed, die-cut laminate labels form no part of the present invention.

A single label-width roll of the laminate labels is then preferably mounted on a high-speed, automatic label-applying apparatus (not illustrated), such as the apparatus manufactured by Accraply, Inc., 15410 Minnetonka Industrial Road, Minnetonka, MN, 55345 U.S.A. or

New Jersey Machine, Inc., 56 Etna Road, Lebanon, NH, 03766-1403, U.S.A. Such apparatus can convey a container, such as the syringe 12, to an indexing wheel, such as a star wheel. Simultaneously, the laminate label roll is unwound adjacent the star wheel, and the release liner layer 207 is pulled back over a conventional peal plate far enough to expose a single-cut label with its adhesive layer 206 in the direct path of the oncoming syringe. As the syringe is carried by the star wheel against the laminate label adhesive, the syringe is also rotated by conventional means about its longitudinal axis. The syringe body makes contact with the leading edge of the awaiting label and continues to be moved by the machine star wheel against the label as the syringe body also rotates, and this pulls the label off of the departing release liner layer 207. The syringe continues to be moved by the star wheel while rotating in contact with the label against a set of pressure rollers that provide continuous contact until the laminate label is completely wrapped around the syringe. The labeled syringe then exits the machine via another indexing star wheel.

The above-described conventional system of applying an oxygen barrier laminate label forms no part of the present invention. The laminate may be alternatively applied by other methods, or manually, to a container, such as a syringe.

According to one aspect of the present invention, the barrier means may include structures other than the above-discussed laminate label structure such as EVOH film, Saran film, and Barex film, or aluminum oxide coated film. For example, a single layer of an oxygen barrier material may be mounted to the surface of the syringe with appropriate attaching means. Also, the barrier means could be mounted to other types of containers, including but not limited to vials, ampules, and the like.

According to another aspect of the invention, the barrier means or barrier structure may be employed also to prevent or reduce ingress or egress of gases other than oxygen, for example, carbon dioxide. As used herein, and in the claims, the term "gas" and the term "gases" are construed to also include water vapor.

It will be readily apparent from the foregoing detailed description of the invention and from the illustrations thereof that numerous variations and modifications may be effected without departing from the true spirit and scope of the novel concepts or principles of this invention.

WHAT IS CLAIMED IS:

1. A system for storing a composition, said system including:

a container adapted for containing said composition and having an exterior, said container having a sidewall structure through which a gas can migrate, said sidewall structure having an outer surface defining part of said exterior; and

means for preventing substantial gas migration through a major portion of said container exterior, said means mounted to at least a portion of said outer surface.

2. The system in accordance with claim 1 in which said means includes a laminate of multiple layers of materials secured with adhesive to said container.

3. The system in accordance with claim 2 in which said laminate is translucent to permit inspection of the container contents.

4. The system in accordance with claim 2 in which said laminate is printed with label information.

5. The system in accordance with claim 1 in which said container is a syringe having a hollow, cylindrical body that is molded from polypropylene and that defines said sidewall structure.

6. The system in accordance with claim 1 in which said means includes a polyester film layer coated with silicon oxide applied by evaporation or gas plasma deposition.

7. The system in accordance with claim 1 in which said means exhibits a relatively low oxygen permeability compared to said sidewall structure.

8. The system in accordance with claim 1 in which said means exhibits a relatively low carbon dioxide permeability compared to said sidewall structure.

9. A system for storing a composition which can be deleteriously affected by oxygen, said system including:

a container adapted for containing said composition and having an exterior, said container having a sidewall structure through which oxygen can migrate, said sidewall structure defining an outer surface having at least a first predetermined area which is a major portion of the container exterior; and

a film secured in face-to-face contact with said outer surface of said sidewall structure over said first predetermined area, said film having relatively low oxygen permeability to provide a barrier to substantial oxygen migration.

10. The system in accordance with claim 9 in which said film includes a laminate of multiple layers of materials secured with adhesive to said container.

11. The system in accordance with claim 10 in which said laminate is translucent to permit inspection of the container contents.

12. The system in accordance with claim 10 in which said laminate is printed with label information.

13. The system in accordance with claim 9 in which said container is a syringe having a hollow, cylindrical body that is molded from polypropylene and that defines said sidewall structure.

14. The system in accordance with claim 9 in which said film includes a layer of polyester coated with silicon oxide applied by evaporation or gas plasma deposition.

15. A system for storing a composition, said system including:

a container adapted for containing said composition and having an exterior, said container having a sidewall structure through which a gas can migrate, said sidewall structure defining an outer surface having at least a first predetermined area which is a major portion of the container exterior; and

a film secured in face-to-face contact with said outer surface of said sidewall structure over said first predetermined area, said film having relatively low permeability to said gas so as to provide a barrier to substantial migration of said gas.

16. The system in accordance with claim 15 in which said film includes a laminate of multiple layers of materials secured with adhesive to said container.

17. The system in accordance with claim 16 in which said laminate exhibits a relatively low permeability for at least one of the gases oxygen, carbon dioxide and water vapor relative to said sidewall structure.

FIG. 1

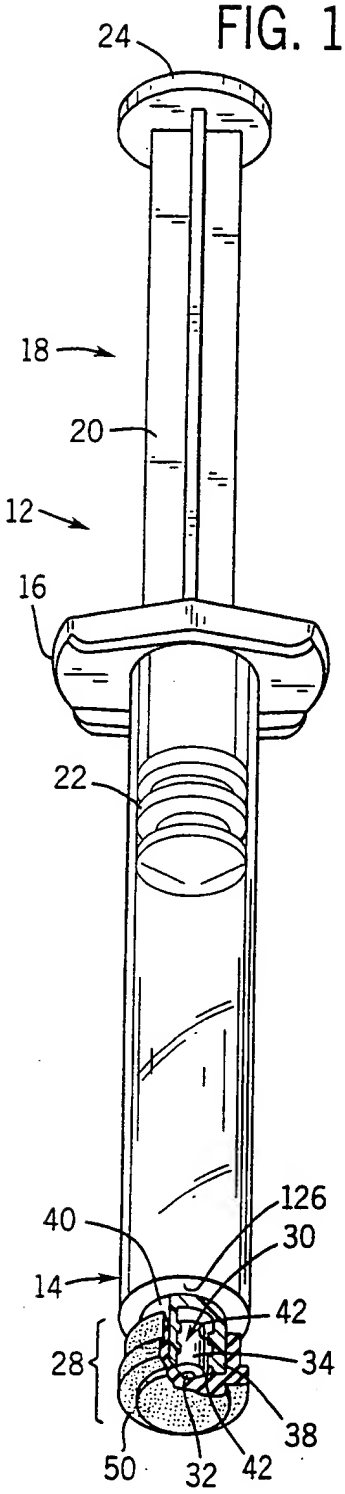


FIG. 2

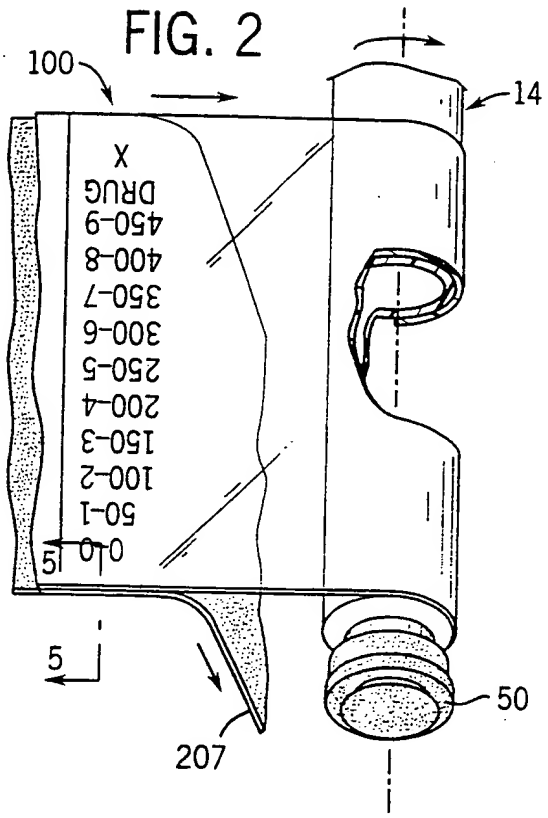


FIG. 3

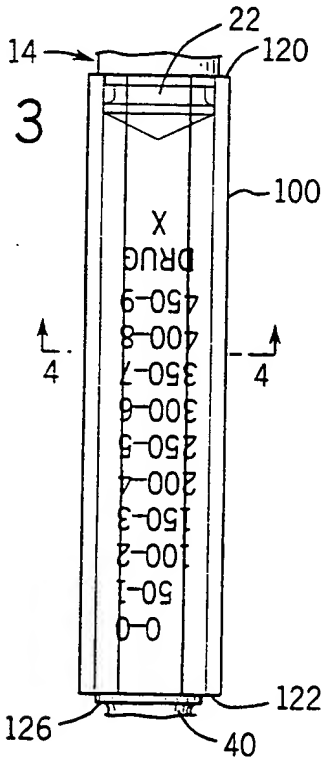


FIG. 4

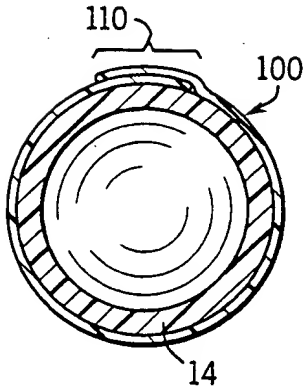
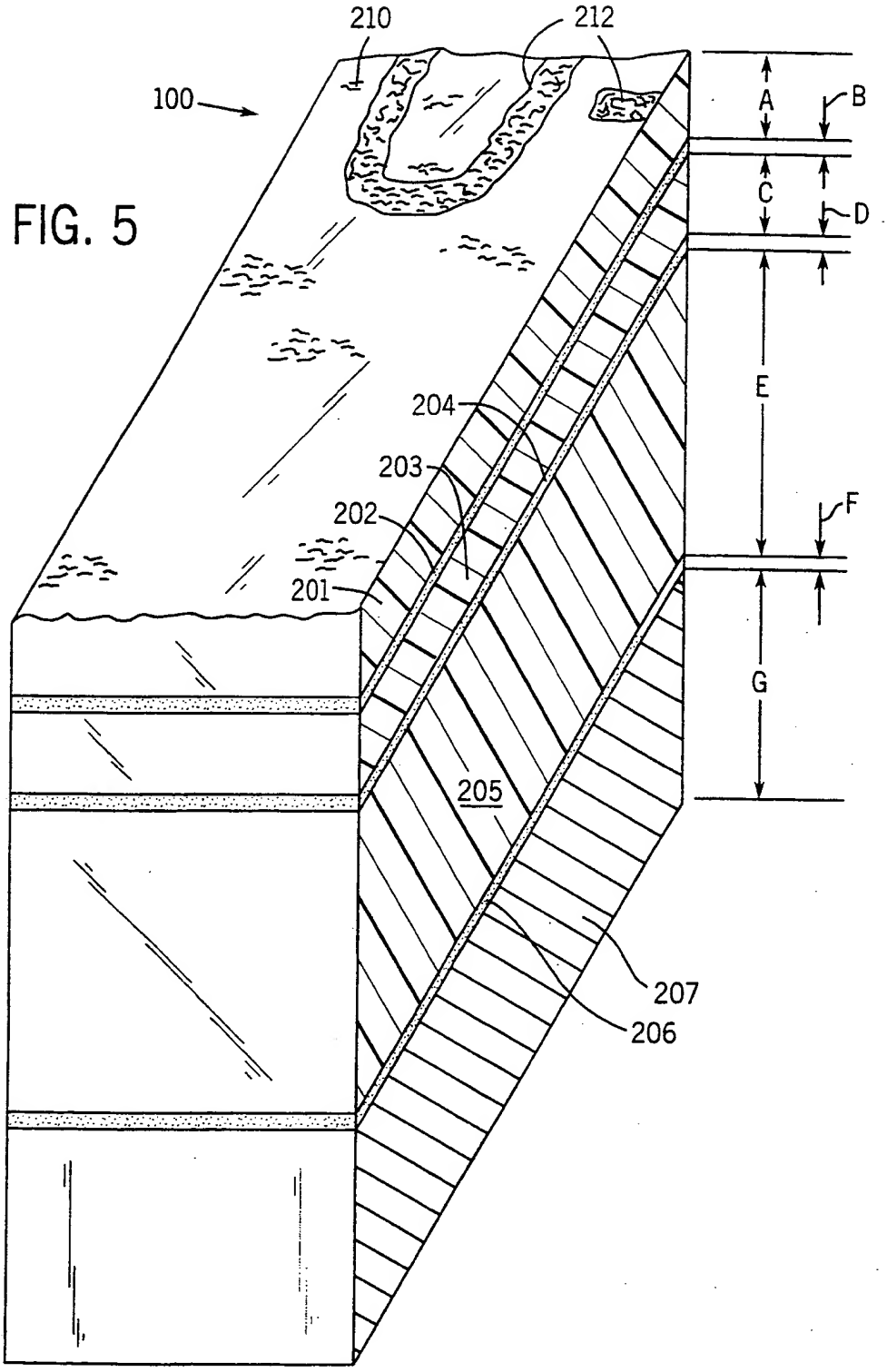


FIG. 5



INTERNATIONAL SEARCH REPORT

Intern. al Application No
PCT/US 98/22464

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61J1/00 A61M5/31

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61J A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 512 612 A (BECTON DICKINSON CO) 11 November 1992 see page 4, line 3 - line 51; figures	1-4, 7-12, 15-17
X	US 4 601 926 A (JABARIN SALEH A ET AL) 22 July 1986 see column 1, line 64 - line 68 see column 3, line 29 - line 45	1,4,7-9, 12,15,17
A	US 4 986 820 A (FISCHER DAN E) 22 January 1991 see column 4, line 44 - line 54	5,13
A	WO 95 07815 A (DAICEL CHEMICAL INDUSTRIES,LTD.) 23 March 1995 see abstract	6,14

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 February 1999	11/02/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Baert, F

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INTERNATIONAL SEARCH REPORT

Interr ıal Application No
PCT/US 98/22464

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 048 997 A (RAGHAVACHARI) 20 September 1977 see column 3, line 45 - line 65; figures 1,2 -----	1,9,15

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Information on patent family members

Intern al Application No
PCT/US 98/22464

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FIG. 1

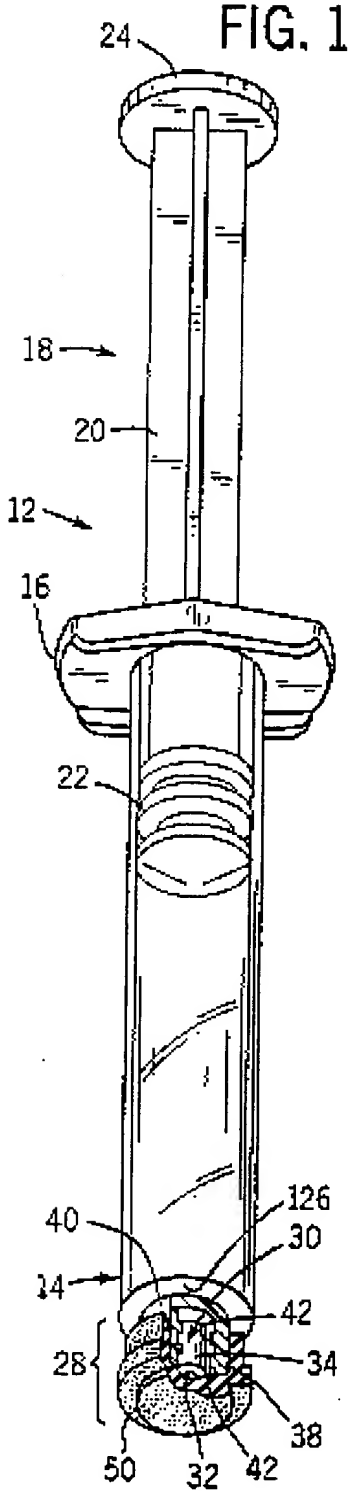

FIG. 2

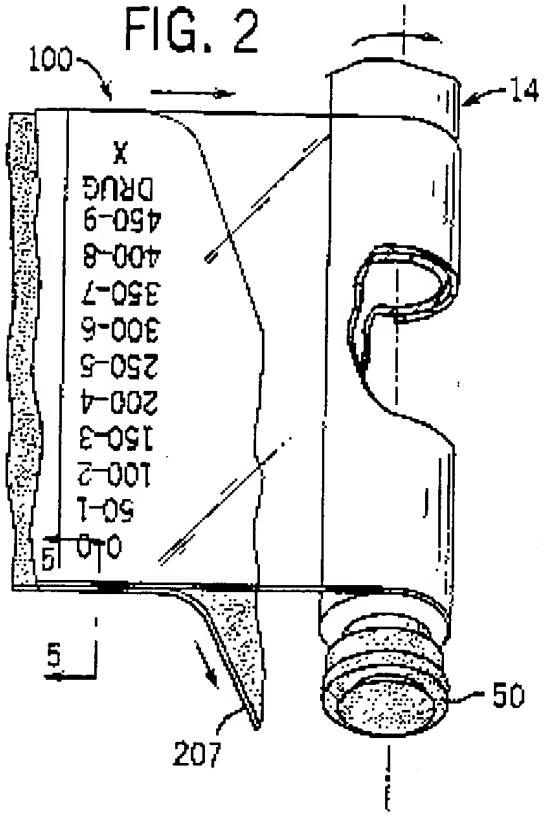

FIG. 3

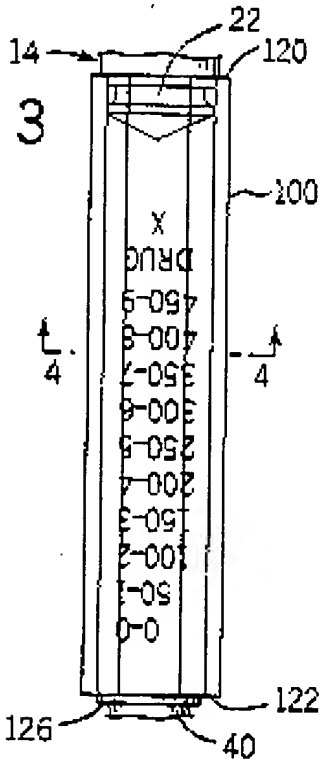

FIG. 4

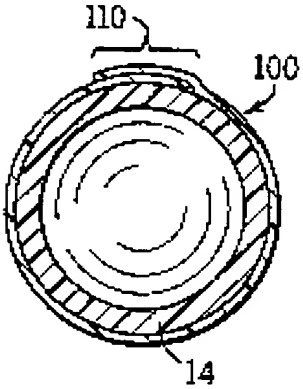

FIG. 5